EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
THIS DOCUMENT RELATES TO:	)	Master File No. 01-CV-12257-PBS
City of New York, et al. v. Abbot Laboratories, et al., Civ. Action No. 04-cv-06054, et al.	)	Hon. Patti B. Saris

ASTRAZENECA'S SUR-REPLY IN FURTHER OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF DATA FOR THE DESIGNATED FUL DRUGS

Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (together "AstraZeneca") respectfully submit this sur-reply in further opposition to Plaintiffs' motion to compel production of data relating to AstraZeneca's Arm-A-Med albuterol sulfate 0.83 mg/ml ("AstraZeneca's albuterol").

PRELIMINARY STATEMENT

Plaintiffs concede that the "question" raised by a FUL fraud claim is whether AstraZeneca's alleged "failure to report true prices to the publishing compendia resulted in a false and inflated FUL to be established." Reply, at 2. But contrary to this Court's order that "plaintiffs must allege that defendants submitted false or inflated published prices which, if truthful, would likely have affected the FUL," Plaintiffs' Complaint is devoid of any such allegation. To satisfy this pleading standard, Plaintiffs must allege an Actual Acquisition Cost (AAC) for a drug subject to a FUL – for present purposes, AstraZeneca's albuterol – that is less

than 2/3 of the applicable FUL.[1]

In response to AstraZeneca's observation that Plaintiffs have not alleged FUL fraud against AstraZeneca's albuterol, Plaintiffs specifically direct the Court to paragraph 280 of their Complaint. But that paragraph fails to mention AstraZeneca's albuterol or any FUL – let alone plead an AAC for AstraZeneca's albuterol that is less than 2/3 of an applicable FUL. Indeed, Plaintiffs implicitly concede their failure to plead FUL fraud against AstraZeneca's albuterol by belatedly and improperly attempting to amend their Complaint in an exhibit to their reply brief on this motion to compel.

Significantly, Plaintiffs' new "allegations" undermine, rather than support, any claim of FUL fraud against AstraZeneca's albuterol. In their new exhibit, Plaintiffs assert that the "Per Package AAC" for AstraZeneca's albuterol was $0.69 between July 1, 1997 and September 30, 1997.[2] The applicable FUL for the period from October 1, 1997 (when a FUL was first applied) through December 2000 (by which time AstraZeneca's albuterol was no longer sold) was $0.60. Because the asserted AAC was more than 2/3 of the FUL, it would not have affected the FUL if AstraZeneca had reported it. Thus, Plaintiffs' own exhibit shows that Plaintiffs do not have a FUL fraud claims against AstraZeneca's albuterol under this Court's standard for pleading FUL fraud.

Under these circumstances, Plaintiffs' motion to compel the production of data relating to AstraZeneca's Arm-A-Med albuterol sulfate should be denied.

---

[1] See Motion to Dismiss Memorandum and Order, at 39 (Apr. 2, 2007) (docket #3979); Transcript of Status Conference, at 32 (May 16, 2007); see also infra at 5.

[2] See Reply, Exh. A.

ARGUMENT

The new arguments Plaintiffs offer in their reply brief are unavailing for several reasons.

First, contrary to the Court's July 30, 2007, Order that "plaintiffs must allege that defendants submitted false or inflated published prices which, if truthful, would likely have affected the FUL," Motion to Dismiss Order ¶ 3 (docket #4540) (emphasis added), Plaintiffs fail to identify any FUL fraud allegation for AstraZeneca's albuterol. In their reply brief, Plaintiffs cite paragraph 280 of their First Amended Consolidated Complaint ("Complaint"), but neither this paragraph nor any other paragraph mentions AstraZeneca's albuterol or any applicable FUL, much less plead an AAC that would have affected the FUL.

Indeed, the only allegation Plaintiffs have ever made in their pleadings with regard to AstraZeneca's albuterol reflects a time span of only one day – January 1, 1997 – a date which in fact preceded the setting of the FUL by nine months.[3] This allegation is insufficient, see Opp. Br., at 5-6, and Plaintiffs abandon it in their reply brief. Absent allegations of an AAC that would have affected the FUL, Plaintiffs fail to show that discovery of AstraZeneca's albuterol is relevant or reasonably calculated to lead to the discovery of admissible evidence. See Opp. Br., at 5.

Plaintiffs essentially concede the insufficiency of their allegations with respect to AstraZeneca's albuterol by attempting to amend their pleadings in an exhibit to their reply brief. Plaintiffs submit an exhibit to their brief asserting an AAC of $0.69 for one NDC of AstraZeneca's albuterol. See Reply, Exh. A. This assertion is new – Plaintiffs did not provide AstraZeneca with the revised table setting forth the AAC they now claim supports their

[3] The FUL for the GCN for albuterol sulfate 0.83 mg/ml was not set until October 1997. See Declaration of Benjamin Allee in Support of AstraZeneca's Sur-Reply in Further Opposition to Plaintiffs' Motion to Compel ("Allee Sur-Reply Dec."), ¶ 2.

discovery request until they served their reply brief – and it represents an impermissible attempt to amend their Complaint in a brief.[4] See In re Tyco Int'l, Ltd. Multidistrict Litig., No. MD-02-1335-B, 2004 WL 532193, at *1 (D.N.H. Mar. 16, 2004). In any case, Plaintiffs' submission of the new assertions with their reply brief demonstrates their own awareness of the insufficiency of their pleadings. Moreover, as set forth below, the new assertions add no support to Plaintiffs' motion.

Second, Plaintiffs' belated assertion of an AAC of $0.69 for AstraZeneca's albuterol in fact undermines Plaintiffs' position, because this asserted price is greater than the price on which the FUL was based, and greater even than the FUL itself, and therefore would have had no impact on the FUL. The FUL from 1997 through 2000[5] for the albuterol sulfate GCN at issue was $0.60. See Allee Sur-Reply Dec., ¶ 2. Because the FUL is set at 150% of the published price for the least costly therapeutic equivalent of the drug, see Motion to Dismiss Memorandum and Order, at 39 (docket #3979), the published price serving as the basis for reimbursement under the FUL scheme is 2/3 of the FUL. The basis for the FUL for albuterol sulfate, therefore, was $0.40 during all relevant times. Even if AstraZeneca had published a price of $0.69 for its albuterol this would have had no impact on FUL reimbursement. The price alleged by Plaintiffs ($0.69) is higher than the price on which the FUL was based ($0.40) and higher even than the

[4] Plaintiffs thus continue the completely backwards approach they have taken to pursuing discovery relating to AstraZeneca's albuterol. As described in AstraZeneca's opposition brief, Plaintiffs filed their motion to compel before serving on AstraZeneca the document requests that apparently served as the basis for their motion. Plaintiffs then served on AstraZeneca those document requests three days before AstraZeneca's opposition to the motion to compel was due to the Court. Plaintiffs use their brand new assertions as the basis for their October 18, 2007 document requests, their January 31, 2008 motion to compel, and their February 12, 2008 document requests.

[5] This is the relevant time period for purposes of this motion, because the FUL for the albuterol sulfate was set in October 1997 and did not change until after December 2000, by which time AstraZeneca's albuterol was no longer being sold. See Allee Sur-Reply Dec., ¶ 2; Declaration of Benjamin Allee in Support of AstraZeneca's Opposition to Plaintiffs' Motion to Compel, ¶ 11 (submitted Feb. 15, 2008).

FUL ($0.60).[6] Plaintiffs' new assertions in the exhibit to their reply brief actually undermine Plaintiffs' motion to compel.

Third, Plaintiffs are wrong that "this Court has specifically ordered that discovery is to proceed on all of the Designated FUL Drugs, without limitation." Reply at 2 (citing CMO #33 ¶ 5). Again, the Court has ordered that "plaintiffs must allege that defendants submitted false or inflated published prices which, if truthful, would likely have affected the FUL." Motion to Dismiss Order ¶ 3 (docket #4540) (emphasis added). Further, on September 14, 2007, the Court issued Case Management Order #33 adopting procedures for targeted discovery "relating to the Designated FUL Drugs," ordering that:

> "plaintiffs and defendants shall engage in such party and third-party discovery as they deem relevant to the prosecution and defense of the claims in the [Complaint] relating to FULs generally; however, there shall be no discovery on particular drugs or NDCs subject to and paid by New York Medicaid based on FULs other than those relating to the Designated FUL Drugs and for such Designated FUL Drugs, discovery is limited to the period 1997 to 2005."

CMO #33 ¶ 5(b) (docket #4690-2) (emphasis added). Plaintiffs appear to read the "however" proviso – which clearly is intended to narrow the scope of discovery ordered in the immediately preceding "shall engage" directive – as somehow overriding the relevance limitation in the "shall engage" directive. But Plaintiffs' reading – under which a proviso intended to narrow the scope of discovery would instead expand it – is entirely unwarranted.[7]

---

[6] With respect to Plaintiffs' theory of AWP fraud, which is not at issue in this motion to compel, the new assertions attached to Plaintiffs' reply brief also purport to show a typical spread greater than 30% for a single NDC of AstraZeneca's albuterol. AstraZeneca is examining the data on which the new assertions are made to determine whether they have any basis, but not in association with expedited FUL fraud discovery, to which AWP-based theories are irrelevant.

[7] Further, Plaintiffs' conflicts with the fundamental relevance limitation on the scope of discovery set forth in the Federal Rules of Civil Procedure. See Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any matter . . . that is relevant to the claim or defense of any party . . . For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.").

Thus, CMO #33 permits only "relevant" discovery, and it does not relieve Plaintiffs of their burden of pleading allegations showing that AstraZeneca "submitted false or inflated published prices which, if truthful, would likely have affected the FUL" applicable to AstraZeneca's albuterol, and establishing how the data they are requesting is relevant to those allegations.

Lastly, Plaintiffs make the "straw man" argument that the de minimis utilization of AstraZeneca's albuterol does not alone defeat Plaintiffs' discovery request, because even a drug minimally used during the relevant time period could have served as the basis for setting the FUL. AstraZeneca, of course, made no such argument, but rather pointed to the minimal utilization of its albuterol during the relevant time period to highlight the disproportionate and senseless consequence of condoning Plaintiffs' efforts to compel discovery of irrelevant materials. Not only is discovery of AstraZeneca's albuterol needless given Plaintiffs' failure to set forth any allegations that the its AAC could have impacted the FUL, but such discovery is absurdly burdensome: acceding to Plaintiffs' overbroad, foundationless requests for AstraZeneca's albuterol materials would likely cost more than the amount Medicaid reimbursed for the drug during the entire relevant time period.[8]

[8] Additionally, Plaintiffs' attempt to argue that AstraZeneca must produce irrelevant materials because other Defendants responding to FUL-focused discovery requests have agreed to produce data for other drugs based on other allegations should be ignored. This is no argument at all, but rather an effort by Plaintiffs to twist their own failure to appreciate the differing circumstances among the Defendants against whom they have brought suit into an assertion that an individual Defendant's objection to discovery requests is somehow suspect. Whether other Defendants have produced materials for other drugs or NDCs based on other allegations is immaterial.

CONCLUSION

For the reasons set forth above, and in AstraZeneca's opposition brief, Plaintiffs' Motion to Compel Production of Data for the Designated FUL Drugs should be denied as against AstraZeneca.

Dated: Boston, Massachusetts
March 7, 2008

Respectfully Submitted,

By: /s/ Katherine B. Schmeckpeper

Nicholas C. Theodorou (BBO # 496730)
Katherine B. Schmeckpeper (BBO #663200)
FOLEY HOAG LLP
155 Seaport Blvd.
Boston, Massachusetts 02210
Tel: (617) 832-1000

D. Scott Wise (admitted *pro hac vice*)
Kimberley Harris (admitted *pro hac vice*)
DAVIS POLK & WARDWELL
450 Lexington Avenue
New York, New York 10017
Tel: (212) 450-4000

Attorneys for Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP